

AUG 29 1996

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**510(K) SUMMARY**  
**RELEASABLE THROUGH FREEDOM OF INFORMATION**

**Pursuant to 513(i) of the Federal Food, Drug, and Cosmetic Act, as Amended.**

**Company Name:** Calcitek, Inc.  
**Address:** 2320 Faraday Avenue, Carlsbad, CA 92008  
**Telephone Number:** (619) 431-9515  
**Registration Number:** 2023141  
**Contact Person:** Donna K. Howard  
**Date Summary Prepared:** May 20, 1996

**Classification Name:** Implant, Endosseous (76DZE)  
**Common/Usual Name:** Dental Implant System  
**Device Trade Name:** Spline Dental Implant System

The primary device used for comparison purposes in this summary is Calcitek's existing Spline Dental Implant System. All implant systems are manufactured in the same facility located in Carlsbad, California.

1. **Intended Use:** The statements of intended use are identical.

"For use in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a free standing single tooth replacement."

2. **Description:** These Class III dental implants are supplied sterile, ready for placement by a licensed dentist. There has been no significant change to the prosthetic components.

3. **Technological Characteristics:**

There has been a modification to the apical portion of the implant body to provide the implant with self tapping capabilities. There has been no change to the materials of this device. The implant bodies are offered in both the untextured and textured surfaces. The interface remains unchanged.

4. **Comparison Analysis:**

The overall design of the implants and prosthetic components are identical to the predicate devices.

**SUMMARY INFORMATION - RELEASABLE THROUGH FOI**